UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

LAURA L. BRILL, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

v.

INVIVYD, INC., TILLMAN U. GERNGROSS, and LAURA WALKER,

Defendants.

Case No.: 1:23-cv-10254-JEK

REPLY IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

ORAL ARGUMENT REQUESTED

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A fundamental precept of securities law is that a plaintiff cannot plead fraud with particularity solely by relying on hindsight. *See ACA Fin. Guar. Corp. v. Advest, Inc.*, 512 F.3d 46, 62 (1st Cir. 2008) (complaint "may not simply contrast a defendant's past optimism with less favorable actual results"). But Plaintiffs attempt to do just that, projecting backward from Oxford's disappointing test results to concoct a theory that the "interaction and combination" of Omicron's spike protein mutations preordained those results.¹

The glaring problem with the Complaint and the Opposition is that Plaintiffs cannot point to a single objective, contemporaneous fact showing that Adagio failed to conduct a "meaningful inquiry" or that the challenged opinions were otherwise objectively or subjectively false.² Plaintiffs' insistence that such an inquiry had to include "interaction and combination" analysis, and that what Adagio disclosed as the bases for its opinions was somehow irrelevant or not "meaningful," is simply Plaintiffs' own hindsight opinion. Differences of scientific opinion are not fraud. *See Leavitt v. Alnylam Pharm., Inc.*, 451 F. Supp. 3d 176, 184-85 (D. Mass. 2020). There is no duty to conduct what Plaintiffs view as the "optimal" science; rather, Adagio's duty was only to speak truthfully. And Adagio explained in detail the bases for its expectations and disclosed that further testing was underway to provide a more conclusive answer as to Omicron.

The Opposition also doubles down on Plaintiffs' "duty to update" claim—that Adagio somehow committed fraud by waiting three business days to disclose the results it received from Oxford. But Plaintiffs offer no authority for the proposition that taking a scant three business days

¹ Unless otherwise specified, defined terms and exhibit references ("Ex.") shall have the same meaning as in Defendants' opening memorandum ("Mem.") (ECF No. 37).

² Despite never directly articulating a "meaningful inquiry" claim in the SAC, the Opposition makes clear that Plaintiffs' falsity theory hinges on that subset of the third prong of *Omnicare*, which provides liability where an issuer omits material facts about the basis for its opinion. *See* ECF No. 39 ("Opp.") at 8-10; *Omnicare, Inc. v. Laborers Dist. Council Const. Indus.*, 575 U.S. 175, 189 (2015). Defendants' opening brief addressed more broadly the theories of falsity set out in the SAC and the several prongs of *Omnicare*.

to perform its own critical review and further analysis of the third-party test results was fraudulent, and a wealth of cases says otherwise.

As to scienter, the Opposition offers none of the usual evidence, *e.g.*, an admission, confidential witness, internal document, or personal benefit showing motive. *See In re Boston Sci. Corp. Sec. Litig.*, 686 F.3d 21, 31 (1st Cir. 2012). All Plaintiffs offer—after abandoning their original theory that Defendants knew the Oxford test results before making the challenged statements—is their own opinion about the adequacy of Adagio's inquiry. As with falsity, mere difference of scientific opinion does not show the required strong inference of scienter. *Shash v. Biogen, Inc.*, 84 F.4th 1, 17 (1st Cir. 2023). Particularly given Adagio's ample cautions, and the absence of any motive, the SAC fails to plead the required strong inference of scienter.

I. Plaintiffs Fail to Establish the Absence of a Meaningful Inquiry

As an initial matter, Plaintiffs do not challenge any of Defendants' statements of present fact, and indeed acknowledge they were "literally accurate." *See* Opp. at 6-7. Plaintiffs challenge the *sufficiency* of the factual explanations Defendants provided to support their opinion regarding ADG20's potential to neutralize Omicron, but do not contest the accuracy of any of those underlying facts. *See id.* at 6 (facts "did not indicate ADG20 would likely neutralize Omicron"). The crux of Plaintiffs' Opposition is then that the challenged opinion statements were misleading because they were not based on a "meaningful inquiry." *Id.* at 8. To so plead, Plaintiffs

[M]ust identify particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.

Pension Tr. v. J. Jill, Inc., 360 F. Supp. 3d 17, 23 (D. Mass. 2018) (quoting *Omnicare*, 575 U.S. at 194). Plaintiffs have failed to meet their burden.

The challenged statements could not have been misleading where Defendants disclosed the bases for their opinions: (i) the Company conducted epitope mapping, structural studies, and sequence analyses on Omicron (SAC ¶¶ 51, 54); (ii) none of the mutations in the spike protein identified by those analyses was associated with escape from ADG20 (id. ¶ 50); and (iii) ADG20 retained neutralization activity against prior variants (id. ¶ 53). Plaintiffs do not dispute this was an accurate disclosure of the bases of Defendants' opinion, but instead seek to disparage this inquiry as not "meaningful" because Adagio purportedly had not also "evaluate[d] the likely effect of the interaction and combination of Omicron's three dozen spike protein mutations on ADG20's effectiveness." Opp. at 8-9. But a "meaningful inquiry" under *Omnicare* does not require conducting every conceivable analysis. See In re Philip Morris Int'l Inc. Sec. Litig., 437 F. Supp. 3d 329, 353 (S.D.N.Y. 2020), aff'd 89 F.4th 408 (2d Cir. 2023) ("[W]here a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement.") (citation omitted); Frankfurt-Tr. Inv. Luxemburg AG v. United Techs. Corp., 336 F. Supp. 3d 196, 228 (S.D.N.Y. 2018), aff'd sub nom. Kapitalforeningen Lægernes Invest v. United Techs. Corp., 779 F. App'x 69 (2d Cir. 2019) (complaint was "replete with detail about the process demonstrating the 'meaningful inquiry'"). It also does not mean conducting the best possible analysis. See In re Sepracor, Inc. Sec. Litig., 308 F. Supp. 2d 20, 36 (D. Mass. 2004) ("The securities laws do not impose a duty to conduct 'good science.""); In re PLC Sys., Inc. Sec. Litig., 41 F. Supp. 2d 106, 121 (D. Mass. 1999) (similar). Further, Plaintiffs' premise that "[t]he individual mutational analysis performed by Adagio was insufficient on its own to indicate whether ADG20 would likely

³ Reframing the argument as a supposed "omission" that Adagio had not analyzed certain data about Omicron's mutations (*see* Opp. at 10) is just semantics and in any case suffers from all the problems identified in Section I. Nevertheless, the Company made clear to investors that it had not done specific analysis on the interaction and combination of Omicron's mutations: "*none of the mutations present in the spike protein* of the Omicron variant have been associated with escape from ADG20 neutralization." *See* Ex. B at 1 (emphasis added); Ex. F at 10 (similar). This clearly refers to the individual mutations in the spike protein.

be effective" (Opp. at 9) is just Plaintiffs' own opinion, not an objective fact.⁴ At bottom, Plaintiffs' claims rest on nothing more than their scientific disagreement about methodology. *See In re Philip Morris Int'l Sec. Litig.*, 89 F.4th 408, 429 (2d Cir. 2023) (claim that "methodology [was] not sound enough" did not support fraud); *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) ("dispute about the proper interpretation of data" not actionable). The MIT research (Opp. at 10) at most shows that Plaintiffs' preferred analysis was feasible. It does not show that it was the only legitimate analysis, much less establish that Adagio's inquiry was not meaningful.⁵

II. The PSLRA Safe Harbor Applies

The challenged statements regarding the expected neutralization activity of ADG20 against Omicron are quintessentially forward-looking. *See Wasson v. LogMeln, Inc.* 496 F. Supp. 3d 612, 634 (D. Mass. 2020) ("A forward-looking statement is what it sounds like—a prediction, projection, or plan."). Plaintiffs' contention that the statements should not be viewed as forward-looking because they supposedly omitted the "current fact" that Adagio "lack[ed]... a meaningful inquiry" makes no sense. Opp. at 11. Whether or not a statement is forward-looking depends on its language. *See Weston v. DocuSign, Inc.*, 669 F. Supp. 3d 849, 874 (N.D. Cal. 2023). And the claimed absence of a meaningful inquiry is not a *fact*; it is Plaintiffs' own opinion. The contention

⁴ Plaintiffs' cases are distinguishable. In *City of Warren Police & Fire Ret. Sys. v. Prudential Fin., Inc.*, the court found that where a confidential witness testified that the company was considering taking a reserve before the challenged statements, and the company took the reserve weeks later, the claim was based on more than hindsight. 70 F.4th 668, 693 (3d Cir. 2023). Such evidence, contemporaneous with the challenged statements, is absent here. Similarly, the court in *N.E. Carpenters Guar. Annuity & Pension Funds v. DeCarlo* relied on objective evidence (also absent here) that suggested that the opinion was false and therefore could not have been based on a meaningful inquiry. 80 F.4th 158, 175 (2d Cir. 2023). So too, in *Lucia v. Prospect St. High Income Portfolio, Inc.*, plaintiff alleged defendants possessed but omitted an unfavorable analysis on bond performance, rendering misleading their discussion of a more favorable one. 36 F.3d 170, 176 (1st Cir. 1994). Plaintiffs allege no analogous study.

⁵ While Drs. Fauci and Collins "urged caution," and Dr. Fauci opined that the "profile" of Omicron suggested it might evade immune protection from a monoclonal antibody, both acknowledged there was uncertainty. *See* Opp. at 7 n.5, 8; Ex. C at 5 (mutations "might not respond as well to protection from the vaccines. But we don't know that"); Ex. D at 4-5 (new mutations "might" evade protections from antibodies or vaccines but "it's not necessarily that that's going to happen"). And neither specifically commented on the need for evaluation of the "interaction and combination" of Omicron's mutations. In any event, these still are scientific opinions.

that Defendants' cautions were not meaningful because they had not analyzed the "interaction and combination" of the mutations (Opp. at 1, 11) is just a flawed spin on Plaintiffs' no "meaningful inquiry" claim. See supra at 2-4. Defendants' cautions concerning variants, plus their disclosure that additional testing was underway, were specific, not boilerplate, and more than sufficient. See Mem. at 12-13; In re Cytyc Corp. Sec. Litig., 2005 WL 3801468, at *21 (D. Mass. Mar. 2, 2005) (cautions need not list precise factor that causes statement not to come true). Finally, Dr. Gerngross' oral statements were clearly forward-looking, and thus Plaintiffs must allege adequately that they were made with actual knowledge they were false or misleading. See 15 U.S.C. § 78u-5(c)(1). As discussed infra, Plaintiffs have failed to provide any particularized allegations from which the Court could infer that Dr. Gerngross had such knowledge. See Section IV. Indeed, there are no facts suggesting the statements were false at all.

III. Defendants Promptly Disclosed the Results of the Oxford Tests

The Opposition proposes that Adagio, upon receipt of the third-party test results from Oxford, should have immediately disclosed them. Opp. at 13. To start, the Opposition conflates the distinct duties to correct and update. *See id.* at 13-16; *In re Burlington Coat Factory Sec. Litig*, 114 F.3d 1410, 1430 (3d Cir. 1997) (distinguishing theories). Regardless, Plaintiffs' arguments fail under either theory. A duty to correct may arise if the speaker learns that a prior statement was misleading *when made* because of specific later-discovered errors. *See Backman v. Polaroid Corp.*, 910 F.2d 10, 16-17 (1st Cir. 1990); *In re Burlington Coat Factory Sec. Litig*, 114 F.3d at 1432 (requiring allegations as to what specific errors made forecast misleading). Here, Plaintiffs'

⁶ Plaintiffs argue the November 29 Press Release's citation to additional risks in the Company's other SEC filings was insufficient because only oral statements may incorporate other statements by reference. Opp. at 12 n.9. This is not the law, and *In re Cytyc Corp. Sec. Litig.*, 2005 WL 3801468, at *21 contains no such limitation. *See Hackel v. AVEO Pharms., Inc.*, 474 F. Supp. 3d 468, 480 (D. Mass. 2020) (approving of cautionary language in press releases that "directed readers to the Company's SEC filings").

claim is based on new data, not discovery of factual errors informing the prior statements. Therefore, the claim is properly characterized as a duty to update claim. *See In re Cabletron Systems, Inc.*, 311 F.3d 11, 36 (1st Cir. 2002) (duty to update could arise if "*later developments* substantially undermined the accuracy of the earlier statements") (emphasis added).

Defendants had no duty to "update" their forward-looking statements. 15 U.S.C. § 78u-5(d); Fisher v. SpecTran Corp., 2001 WL 34644311, at *5 (D. Mass. May 31, 2001) (duty to update "severely limited and undermined by [] the PSLRA"). Plaintiffs concede as much. See Opp. at 15 ("Yet, the PSLRA section they cite only applies to forward-looking statements and says only that the statute itself does not create a duty to update."). That concession is fatal: the PSLRA bar would be meaningless if a plaintiff could simply circumvent it by pointing to some other source of duty. Nor does SEC guidance "encourag[ing]" companies to consider disclosures regarding the impact of COVID-19 on their business supersede the PSLRA. See Opp. at 15; Coronavirus (COVID-19), Div. Corp. Fin. Sec. & Exch. Comm'n, CF Disclosure Guidance: Topic No. 9 (Mar. 25, 2020), https://www.sec.gov/corpfin/coronavirus-covid-19. In any event, the Company did promptly update investors after receiving the test results from Oxford. That Oxford had analyzed the data (Opp. at 13-14) does not mean that Adagio had to make an immediate public disclosure before performing its own critical review and further internal analysis of the results. See In re Genzyme Corp. Sec. Litig., 754 F.3d 31, 44 (1st Cir. 2014) (proper for company to "open an inquiry into the matter, and to wait for a complete picture to become apparent before making any formal announcements").7 Three business days hardly bespeaks fraud and indeed is consistent with SEC guidance. See SEC, Current Report Pursuant to Section 13 or 15(d) of the Securities

⁷ See In re Boston Sci. Corp. Sec. Litig., 686 F.3d at 31 ("irresponsibl[e]" not to investigate); N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc., 537 F.3d 35, 58 (1st Cir. 2008) (similar); Higginbotham v. Baxter Int'l, Inc., 495 F.3d 753, 760-61 (7th Cir. 2007) ("Taking the time necessary to get things right is both proper and lawful.").

Exchange Act of 1934, Form 8-K (General Instructions), https://www.sec.gov/files/form8-k.pdf (requiring filing within four business days after triggering event). Not surprisingly, Plaintiffs do not cite a single case where an issuer was found to have committed fraud by taking such a short period to investigate a matter before disclosing.⁸ And in any event, any investor who purchased in the interim (Opp. at 14) already was on notice that there was no guarantee the testing underway would bear out Adagio's previously expressed hopes. *See Higginbotham*, 495 F.3d at 761.⁹

IV. Plaintiffs Fail to Plead the Required Strong Inference of Scienter with Particularity

Plaintiffs argue that Defendants knowingly or recklessly chose to announce that ADG20 would likely neutralize Omicron when they had not evaluated existing data in the manner necessary to reasonably support such a belief. Opp. at 17. This is yet another version of the flawed claim that Defendants should have conducted the "interaction and combination" analysis that Plaintiffs, with the benefit of hindsight, would have preferred. Just as scientific disagreement alone does not plead a false or misleading statement, it is insufficient to plead a strong inference of scienter with the particularity required. *See In re Sepracor, Inc.*, 308 F. Supp. 2d at 35-36.

Plaintiffs next argue Omicron's structure was known and Defendants knew or should have known that it was nothing like previous variants. Opp. at 18 n.14. But this ignores that the Complaint fails to allege contemporaneous facts showing Defendants knew (or were reckless in not knowing) that Omicron's new structure would inevitably alter ADG20's ability to neutralize

⁸ Plaintiffs assert that the reasonableness of the time between receiving the Oxford results and the Company's December 14 press release should be reserved for the finder of fact, but even in Plaintiffs' cited cases (Opp. at 14-15), the court determined reasonableness as a matter of law. Plaintiffs' other authorities are easily distinguishable. See Sawant v. Ramsey, 2010 WL 3937403, at *18 (D. Conn. Sept. 28, 2010) (question of fact where defendants waited a month to correct press statement about Wal-Mart relationship, where Wal-Mart had complained within hours that it was false); Finnerty v. Stiefel Labs., Inc., 756 F.3d 1310, 1319 (11th Cir. 2014) ("[W]e do not decide whether [defendant] had an immediate duty to update the public" on negotiations with potential acquirer, noting "it may well be desirable to entrust the timing of disclosures to the business judgment of corporate officers where, as here, a duty to update exists but silence would yield benefits for investors as a group, so long as the company and its insiders abstain from trading in the company's securities during this period of nondisclosure").

⁹ Plaintiffs' half-hearted reference to scheme liability does not support a claim. See Opp. at 16 n.12; Mem. at 20 n.12.

the variant. See Metzler Asset Mgmt. GmbH v. Kingslev, 928 F.3d 151, 165 (1st Cir. 2019) (no scienter where plaintiffs failed to allege "that anyone in the company had knowledge regarding the drug's safety profile and sales that contradicted the company's public representations"). To the contrary, Adagio explained in detail to investors the bases for its belief, and Plaintiffs cite only their own scientific opinion to argue Adagio knew or should have known this was insufficient. See Leung v. bluebird bio, Inc., 599 F. Supp. 3d 49, 63 (D. Mass. 2022) ("Plaintiff's assertion that the FDA was 'highly likely to reject bluebird's plan' . . . amounts to Plaintiff's own scientific opinion, which is insufficient support a claim of securities fraud."); Harrington v. Tetraphase Pharms. Inc., 2017 WL 1946305, at *5 (D. Mass. May 9, 2017) (no scienter where "various scientific opinions . . . show[ed] there was disagreement in the scientific community"). Conspicuously lacking are the type of factual allegations which courts typically require to show scienter: admissions, witness statements, or internal documents showing Defendants were aware that interaction and combination analysis would yield negative results. Compare Opp. at 18 with Shash, 84 F.4th at 15; Yan v. ReWalk Robotics Ltd., 973 F.3d 22, 40 (1st Cir. 2020); In re Ariad Pharms., Inc. Sec. Litig., 842 F.3d 744, 751 (1st Cir. 2016). Plaintiffs only rely on the later MIT analysis, and the Oxford results—not any admissions or particularized *contemporaneous* facts.

As to motive, Plaintiffs resort to mere speculation in alleging that Defendants intentionally rushed out the November 29 Press Release to rebut Dr. Fauci's statements before the market opening the following Monday. Opp. at 18. In any event, a purported motive to maintain market price is universally rejected as generic and one which all corporate officials share. *See In re K-tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 895 (8th Cir. 2002); *Kalnit v. Eichler*, 264 F.3d 131, 139-40 (2d Cir. 2001). What is required are allegations of personal benefit, which are absent here. *See Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 82 (1st Cir. 2002). Plaintiffs' reliance on *Matrixx*

Initiatives, Inc. v. Siracusano, 563 U.S. 27 (2011) and Constr. Indust. & Laborers Joint Pension Tr. v. Carbonite, Inc., 22 F.4th 1 (1st Cir. 2021) is misplaced. In Matrixx, plaintiffs alleged particularized facts showing that defendants both knew about the adverse events (loss of smell) caused by the company's drug product and took steps to prevent disclosure of the adverse events "because it understood their likely effect on the market." 563 U.S. at 45, 49. Plaintiffs allege nothing like that here. Carbonite involved promotion of a product that the company knew never worked, and—unlike here—defendants had been exposed to "information that either rendered their public statements false or necessarily invited further investigation." 22 F.4th at 10-11.

Plaintiffs next point to the December 14 press release announcing the results of the *in vitro* testing as itself evidencing scienter. Opp. at 19. According to the theory, the statement that ADG20's reduction in neutralization activity against Omicron "was not suggested by prior data" was false and a "cover-up" because "analysis of the 'combination of mutations' documented in 'prior data' would have confirmed that neutralization was unlikely." *Id.* As an initial matter, this is illogical: it assumes its conclusions both that the initial statements were misleading and that Adagio believed a "cover-up" was necessary. Moreover, the December 14 press release makes clear that the "prior data" to which Defendants referred is the information on which the Company actually relied and explicitly disclosed in forming the initial opinion, not data that hypothetically would have been obtained from an analysis that was not conducted. *See* Ex. G at 1. Defendants' statement must be read in context. *See In re Karyopharm Therapeutics Inc., Sec. Litig.*, 552 F.

¹⁰ In re MicroStrategy, Inc. Sec. Litig., 115 F. Supp. 2d 620, 641 (E.D. Va. 2000) (alleging scienter where "correcti[ve]" disclosure was false because it claimed revised restatement was result of updated guidance on accounting principles, rather than violation of long-standing accounting principles) and In re Nature's Sunshine Prods. Sec. Litig., 486 F. Supp. 2d 1301, 1310 (D. Utah 2007) (alleging scienter via company's failure to take remedial actions requested by auditor, suspicious insider trading, and misstatements on effect of alleged fraud) are inapposite. ¹¹ As explained in their opening brief, each of Defendants' exhibits is properly before the Court. See Mem. at 2 n.3; Opp. at 5 n.4; ECF No. 38, Kolovos Decl. Exs. A-L. Exhibits A-H and L are each expressly referenced in the Complaint. See SAC ¶ 31, 47-48, 50-51, 56-57, 59(b)-(c),61-62. Exhibits J and K are Adagio's public 10-Q filings.

Supp. 3d 77, 87 (D. Mass. 2021), aff'd sub nom. Thant v. Karyopharm Therapeutics Inc., 43 F.4th 214 (1st Cir. 2022) (rejecting plaintiff's attempt to separate statement from its context).

Plaintiffs further argue that during the short interval in which Defendants had the *in vitro* results from Oxford before disclosing them, they "*knew* investors were actively being misled and damaged." Opp. at 20. But Plaintiffs posit no motive for this purported "delay," and the "opposing" non-culpable inference—that the Company took the short amount of time necessary to conduct a reasonable inquiry and understand the results before disclosing them—is far more compelling (and certainly "at least as compelling"). *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 314 (2007); *supra* Section III. Moreover, investors in the interim period were not "misled"—they knew the risk that the *in vitro* testing underway might yield negative results and could not reasonably have expected instant disclosure. *See Higginbotham*, 495 F.3d at 761. ¹²

V. Plaintiffs Should Not Be Granted Further Leave to Amend the Complaint

Despite Plaintiffs' token request for further leave to amend (Opp. at 20), dismissal here should be with prejudice. A "district court enjoys significant latitude in deciding whether to grant leave," and grounds to deny leave include "repeated failure to cure deficiencies" by previous amendments. *ACA Fin. Guar. Corp.*, 512 F.3d at 55-56 (1st Cir. 2008) (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)). Here, Plaintiffs have already amended multiple times. *See* ECF Nos. 28, 32. Moreover, Plaintiffs provide no "reasons supporting their request" nor the "substance of possible amendments." *Silverstrand Invs. v. AMAG Pharm., Inc.*, 707 F.3d 95, 107 (1st Cir. 2013).

VI. Conclusion

For these reasons and those in Defendants' opening memorandum, the Court should dismiss the Second Amended Complaint in its entirety, with prejudice and without leave to amend.

¹² Because Plaintiffs have failed adequately to allege any Section 10(b) violations, the control person claims also must be dismissed. *See* Mem. at 20; *Metzler Asset Mgmt.*, 928 F.3d at 158 n.3.

Dated: March 27, 2024 Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Peter J. Kolovos, hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing on this 27th day of March, 2024.

/s/ Peter J. Kolovos Peter J. Kolovos